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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/679,234

10/03/2003

El Gendler

213189

3542

23460

7590

04/19/2006

LEYDIG VOIT & MAYER, LTD
TWO PRUDENTIAL PLAZA, SUITE 4900
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CHICAGO, IL 60601-6780

EXAMINER

DAVIS, RUTH A

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/679,234

Applicant(s)

GENDLER ET AL

Examiner

Ruth A. Davis

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 11-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1 – 10 in the reply filed on March 14, 2006 is acknowledged. The traversal is on the ground(s) that there is no burden to search all of the groups because the search is overlapping. This is not found persuasive because while the search for the various groups may overlap, an overlapping search is not a coextensive search. Thus, an anticipatory reference for one group may not anticipate or even make obvious the invention of another group. Therefore, the groups do, in fact, require separate searches and would therefore place an undue burden on examiner

The requirement is still deemed proper and is therefore made FINAL.

Claims 11 – 32 are withdrawn from consideration as being drawn to non-elected subject matter. Claims 1 – 10 have been considered on the merits.

Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims directed to the process of making or using a patentable product, previously withdrawn from consideration as a result of a restriction requirement are subject to being rejoined if they include all the limitations of the allowable product.

Specification

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see page 2). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 2 – 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 2 and 3 are drawn to an implant however are rendered vague and indefinite for reciting “comprising” in line 1, because the limitation is considered to broaden the claim from which it depends. Claim 1 is drawn to an implant “consisting essentially of” particular components whereas claims 2 and 3 include a broader limitation by reciting the term “comprising”. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by “such as” and then narrow language. The Board stated that this

Art Unit: 1651

can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1 – 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gendler (US 4932973) in view of Jefferies (US 5948426).

Art Unit: 1651

Applicant claims an implant consisting essentially of organic bone matrix with perforations populated with live human undifferentiated cells suspended in a gel, wherein the perforations are capable of stimulating transformation of the cells into differentiated cartilage and bone cells. The gel is a bone gel comprising demineralized bone matrix and water, specifically demineralized bone matrix and human blood serum or a component thereof. The cells are derived from blood, bone marrow, the spleen, adipose tissue, the placenta, umbilical cord or an embryo.

Gendler teaches an implant for inducing bone and cartilage formation, comprising a perforated organic bone matrix, wherein the implant induces bone formation (abstract, col.2-4)

Gendler does not teach the implant further comprising undifferentiated cells. However, Jefferies teaches a composite bone implant for inducing bone formation wherein stem cells are added to increase development of the bone components (col.6). Specifically, the stem cells (undifferentiated cells) are combined with demineralized bone matrix and water (col.3). The mixture is then combined with the collagen implant (col.4). At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to add undifferentiated cells to the organic bone matrix of Gendler for the known advantage of increasing bone component development, as disclosed by Jefferies. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Jefferies to include undifferentiated cells in the bone matrix of Gendler with a reasonable expectation for successfully obtaining an effective implant for inducing bone.

Although the reference does not identify each of the claimed sources of stem cells (undifferentiated cells), these limitations are considered to be product by process. Thus, the

Art Unit: 1651

patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113). In spite of this fact, each of the claimed sources were well known sources of stem cells (undifferentiated cells). Thus it would have been well within the purview of one of ordinary skill in the art to obtain the stem cells of Jefferies from any of the claimed sources as a matter of standard experimental practice and procedure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 - 2:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1651

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

April 14, 2006
AU 1651

A handwritten signature in black ink, appearing to read 'R. Davis', with a stylized, cursive script.

RUTH A. DAVIS
PATENT EXAMINER